

PCT

WORLD INTELLECTUAL PROPE
International Bu

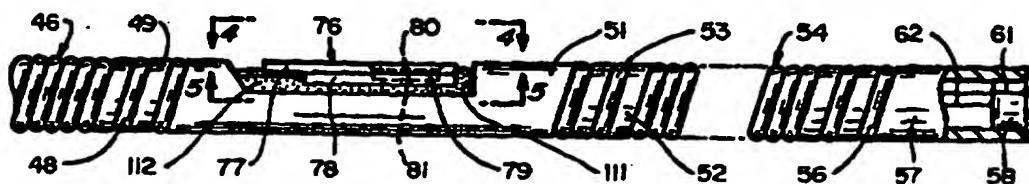


(6)

INTERNATIONAL APPLICATION PUBLISHED UNDER

WO 9607351A1

(51) International Patent Classification 6 : A61B 5/00	A1	(11) International Publication Number: WO 96/07351 (43) International Publication Date: 14 March 1996 (14.03.96)
(21) International Application Number: PCT/US95/09898		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
(22) International Filing Date: 4 August 1995 (04.08.95)		
(30) Priority Data: 08/300,445 2 September 1994 (02.09.94) US		Published <i>With international search report.</i>
(71) Applicant: CARDIOMETRICS, INC. [US/US]; 645 Clyde Avenue, Mountain View, CA 94043 (US).		
(72) Inventors: CORL, Paul, D.; 3883 El Centro Street, Palo Alto, CA 94306 (US). OBARA, Robert, Z.; P.O. Box 61362, Sunnyvale, CA 94088 (US). ORTIZ, John, E.; 1192 Garden Street, East Palo Alto, CA 94303 (US).		
(74) Agents: HOHBACH, Harold, C. et al.; Flehr, Hohbach, Test, Albritton & Herbert, Suite 3400, 4 Embarcadero Center, San Francisco, CA 94111-4187 (US).		
(54) Title: ULTRA MINIATURE PRESSURE SENSOR AND GUIDEWISE USING THE SAME AND METHOD		



(57) Abstract

This invention is a guidewire (21) having pressure sensing capabilities for measuring pressure of a liquid in a vessel comprising a flexible elongate member (41) and having proximal (42) and distal (43) extremities, and having an outside diameter of 0.018" or less. The distal extremity of said flexible elongate member (41) is adapted to be disposed in the liquid in said vessel. A housing (51) is carried by the flexible elongate member (41) and has a diameter substantially the same as the diameter of the flexible elongate member (41). The housing (51) has a space therein with a pressure sensor (76) mounted in the housing space in the housing. The pressure sensor (76) has a diaphragm (79) formed in a crystal (77) of semiconductor material, that is sensitive to changes in pressure of the liquid in the vessel. The diaphragm (79) is rectangular in shape and is mounted in a well (84), and is bordered by a rim (86) surrounding the well (84). A backing plate (78) is formed of an insulating material bonded to the crystal (77) and serves to reinforce the rim (86) of the crystal (77). The backing plate (78) has a cavity (101) therein underlying the diaphragm and is in substantial registration with the diaphragm (79). The cavity (101) serves as a pressure reference.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LJ	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

-1-

**ULTRA MINIATURE PRESSURE SENSOR AND
GUIDEWIRE USING THE SAME AND METHOD**

This invention relates to an ultra miniature pressure sensor and guidewire and apparatus using the same and method, which is particularly suitable for making pressure measurements in coronary arteries of human beings.

5 It has been well known that it is desirable to make pressure measurements in vessels and particularly in coronary arteries with the advent of angioplasty. Typically in the past, such pressure measurements have been made by measuring the pressure at a proximal 10 extremity of a lumen provided in a catheter advanced into the coronary artery of interest. However, such an approach has been less efficacious as the diameters of the catheters became smaller with the need to advance the catheter into smaller vessels. This made necessary the 15 use of smaller lumens which gave less accurate pressure measurements and in the smallest catheters necessitated the elimination of such a pressure lumen entirely. In an attempt to overcome these difficulties, ultra miniature pressure sensors have been proposed for use on the distal 20 extremities of catheters. However, it has not been feasible prior to the present invention to provide such ultra miniature pressure sensors which are capable of being incorporated in a guidewire for making pressure

-2-

measurements in a very small arterial vessels. There is therefore a need for a new and improved ultra miniature pressure sensor and a guidewire and apparatus utilizing the same.

5 In general it is an object of the present invention to provide an ultra miniature pressure sensor and guidewire and apparatus utilizing the same making possible pressure and velocity measurements.

Another object of the invention is to provide a
10 sensor which can be utilized on the distal extremity of a guidewire .018" or .014" in diameter.

Another object of the invention is to provide a sensor of the above character which is formed of a silicon chip of a small dimension which is reinforced by an
15 additional member to provide reinforcement for the chip.

Another object of the invention is to provide a sensor of the above character in which a thin diaphragm is formed in the crystalline silicon chip.

Another object of the invention is to provide a
20 sensor of the above character in which the reinforcing member extends for approximately 200 microns beyond the silicon diaphragm.

Another object of the invention is to provide a
25 guidewire with the above character in which the number of conducting wires required is kept to a minimum.

Another object of the invention is to provide a
guidewire and method in which simultaneous pressure and
velocity measurements can be made.

Another object of the invention is to provide a
30 guidewire of the above character in which the diaphragm area has been maximized.

Another object of the invention is to provide a
guidewire with the above character in which two pressure
sensors are provided on the guidewire which are spaced
35 apart so that pressure measurements can be made on both sides of a stenosis.

-3-

Another object of the invention is to provide a guidewire of the above character in which the sensors are covered to prevent the formation of blood clots.

5 Another object of the invention is to provide an apparatus of the above character which includes a guidewire with an integral inflatable balloon.

Another object of the invention is to provide an apparatus of the above character in which temperature compensation can be provided.

10 Another object of the invention is to provide an apparatus of the above character which can be utilized in a half-bridge configuration.

15 Additional features and objects of the invention will appear from the following description in which the preferred embodiments are set forth in detail in conjunction with the accompanying drawings.

Figure 1 is a schematic illustration showing use of a guidewire incorporating a pressure sensor of the present invention and apparatus utilizing the same in conjunction 20 with a patient undergoing a catheterization procedure for diagnosis or treatment.

Figure 2 is a side elevational view of a guidewire incorporating an ultra miniature pressure sensor of the present invention.

25 Figure 3 is an enlarged side elevational view of the distal extremity of the guidewire shown in Figure 2 and showing the pressure sensor mounted therein.

Figure 4 is a top plan view looking along the line 4-4 of Figure 3.

30 Figure 5 is a bottom plan view looking along the line 5-5 of Figure 3.

Figure 6 is an isometric view of the pressure sensor shown in Figures 3, 4 and 5 with the lead wires connected thereto.

35 Figure 7 is a side elevational view of the pressure sensor shown in Figure 6.

-4-

Figure 8 is a top plan view of the pressure sensor shown in Figures 6 and 7.

Figure 9 is a cross-sectional view taken along the line 9-9 of Figure 8.

5 Figure 10 is a cross-sectional view taken along the line 10-10 of Figure 8.

Figure 11 is a cross-sectional view taken along the line 11-11 of Figure 8.

10 Figure 12, is a schematic diagram of the circuitry utilized in the pressure sensor shown in Figures 6-11.

Figure 13 is a side elevational view of the distal extremity of another guidewire incorporating the pressure sensor with the sensor of the present invention being mounted in the tip housing.

15 Figure 14 is a side elevational view of the distal extremity of a guidewire having first and second pressure sensors mounted in the distal extremity of the same spaced apart to permit simultaneous measurements of proximal and distal pressures with respect to a stenosis.

20 Figure 15 is a partial side elevational view of another guidewire incorporating the present invention with an enclosed pressure sensor.

25 Figure 16 is a side elevational view partially in section of the distal extremity of another guidewire incorporating the present invention in which the pressure sensor is enclosed in a transition housing.

Figure 16A is a side elevational view in section showing an end-mounted pressure sensor incorporating the present invention.

30 Figure 17 is a side elevational view in section of a guidewire housing a tip-mounted sensor incorporating the present invention with an integral balloon.

In general, the guidewire of the present invention having pressure sensing capabilities is comprised of a 35 flexible elongate element having proximal and distal extremities and having a diameter of .018" and less. The pressure sensor is mounted on the distal extremity of a

-5-

flexible elongate element. It is comprised of a crystal semiconductor material having a recess therein and forming a diaphragm bordered by a rim. A reinforcing member is bonded to the crystal and reinforces the rim of the 5 crystal and has a cavity therein underlying the diaphragm and exposed to the diaphragm. A resistor having opposite ends is carried by the crystal and has a portion thereof overlying a portion of the diaphragm. Leads are connected to opposite ends of the resistor and extend within the 10 flexible elongate member to the proximal extremity of the flexible elongate member.

More in particular, the guidewire 21 of the present invention having pressure measuring capabilities as shown in Figure 1 is one that is adapted to be used in 15 connection with a patient 22 lying on a table or a bed 23 in a cath lab of a typical hospital in which a catheterization procedure such as for diagnosis or treatment is being performed on the patient. The guidewire 21 is used with apparatus 24 which consists of 20 a cable 26 which connects the guidewire 21 to an interface box 27. Interface box 27 is connected by another cable 28 to a control console 29 which has incorporated as a part thereof a video screen 31 on which a waveform 32 displaying ECG measurements may be provided as well as two 25 traces 33 and 34 displaying pressure measurements being made by the guidewire 21.

The guidewire 21 is shown more in detail in Figure 2 and as shown therein, the guidewire 21 can be constructed utilizing the various constructions as shown in Patent 30 Nos. 5,125,137; 5,163,445; 5,178,159; 5,226,421; and 5,240,437. As disclosed therein, such a guidewire consists of a flexible elongate element 41 having a proximal and distal extremities 42 and 43 and which can be formed of a suitable material such as stainless steel 35 having an outside diameter for example of 0.018" or less and having a suitable wall thickness as for example, 0.001" to 0.002" and conventionally called a "hypotube"

-6-

having a length of 150-170 centimeters. Where a smaller guidewire is desired, the hypotube 41 can have an exterior diameter of .014" or less. Typically such a guidewire includes a core wire (not shown) of the type disclosed in 5 the above identified patents which extends from the proximal extremity to the distal extremity of the flexible elongate element 41.

A coil spring 46 is provided and is formed of a suitable material such as stainless steel. It has an 10 outside diameter of 0.018" and is formed from a wire having a diameter of 0.003". The spring 46 is provided with a proximal extremity 47 which is threaded onto the distal extremity 43 of the flexible elongate member 41. The distal extremity 48 of the coil spring 46 is threaded 15 onto the proximal extremity 49 of an intermediate or transition housing 51 formed of a suitable material such as stainless steel having an outside diameter of 0.018" and having a suitable wall thickness as for example, 0.001" to 0.002". The housing 51 is provided with a 20 distal extremity 52 which has the proximal extremity 53 of a coil spring 54 threaded thereon. The coil spring 54 is formed of a highly radiopaque material such as palladium or a tungsten platinum alloy. The coil spring 46 can have a suitable length as for example 27 centimeters whereas, 25 the coil spring 54 can have a suitable length such as 3 centimeters. The intermediate or transition housing 51 can have a suitable length as for example, one to five millimeters. The coil 54 is provided with a distal extremity which is threaded onto an end cap 57 also formed 30 of a suitable material such as stainless steel and having an outside diameter of 0.018" and a wall thickness of 0.001" to 0.002". An ultrasonic transducer 58 is mounted in the end cap in a manner described in Patent No. 5,125,137 and has conductors 61 and 62 secured to the 35 front and rear sides of the same which extend interiorly to the proximal extremity of the flexible elongate member 41.

-7-

A torquer 66 of the type described in Patent No. 5,178,159 is mounted on the proximal extremity 42 of the flexible elongate member 41 for causing a rotation of a guidewire 21 when used in connection with catheterization procedures in a manner well known to those skilled in the art.

The proximal extremity 42 is also provided with a plurality of conducting sleeves (not shown) of the type disclosed in Patent No. 5,178,159. In the present invention, one or more additional sleeves can be provided to make connection to the conductors hereinafter described. The proximal extremity 42 of the flexible elongate member is removably disposed within a housing 68 of the type described in Patent No. 5,178,159 and co-pending applications 128,835 and 114,767 that makes electrical contact with the sleeves on the proximal extremity 42 while permitting rotation of the sleeves and the flexible elongate member 41. The housing 68 carries female receptacles (not shown) which receive the sleeves and which are connected to a cable 71 connected to a connector 72. The connector 72 is connected to another mating connector 73 carried by the cable 26 and connected into the interface box 27.

The portion of the guidewire 21 therefore described is substantially conventional. In accordance with the present invention it is provided with a pressure measuring capability in the form of a pressure sensor assembly 76 which is mounted within the intermediate or transition housing 51. The pressure sensor assembly 76 consists of a diaphragm structure 77 supported by a base plate 78. The diaphragm structure 77 is formed of suitable materials such as "n" type or "p" type 100 oriented silicon with a resistivity of approximately 6-8 ohm-centimeters. The diaphragm structure 77 is a die made from such a wafer. In accordance with the present invention, the die has a suitable length, as for example, 1050 microns and for a 0.014" guidewire has a width of 250 microns and for a

-8-

0.018" guidewire has a width of between 250 and 350 microns. It can have a suitable thickness, as for example, 50 microns. A rectangular diaphragm 79 is formed in the diaphragm structure 77 of a suitable thickness, as 5 for example, 2.5 microns and having dimensions such as a length of 350 microns. The diaphragm 79 has first and second or top and bottom surfaces 80 and 81. The diaphragm is formed by utilization of conventional masking and crystal etching techniques which create a die with two 10 parallel sloping endwalls 82 and two parallel sidewalls 83 extending at right angles to the end walls 82 leading down to the top surface 80 of the diaphragm 79 to form a well 84. As hereinafter explained, the diaphragm 79 is made relatively wide in comparison to the diaphragm structure 15 77 so that what remains is a relatively narrow rim 86 formed by side portions 87 and 88 and an end portion 89. As can be seen from Figures 6, 7 and 8, the diaphragm 79 is located at or near one end of the diaphragm structure or die 77. It has been found that it is desirable to 20 provide a rectangular geometry for the diaphragm 79 rather than a square geometry in order to obtain the highest possible sensitivity for pressure measurements. For example, it has been found that the rectangular diaphragm provides approximately 1.5 times more sensitivity than 25 does a square diaphragm for the same diaphragm thickness and width.

In etching the well 84 to form the diaphragm 81, an impurity can be implanted into the backside of the diaphragm structure 77 before the etching process is 30 commenced so that etching will stop at the desired depth, as for example, within 2 to 3 microns of the bottom surface 81 to provide a diaphragm 79 having a thickness ranging from 2 to 5 microns, and for example, the preferred thickness of 2.5 microns. Because the rim 86 35 provided on the diaphragm structure 77 surrounding the rectangular diaphragm 79 is relatively thin, the base

-9-

plate 78 provides support for this rim to provide the necessary strength for the pressure sensor 76.

In order to obtain adequate performance characteristics such as sensitivity in the miniaturized 5 pressure sensor assembly 76 hereinbefore described, it has been found desirable to have as much of the width of diaphragm structure 77 as possible be occupied by the diaphragm 79 and at the same time to minimize the portion of the diaphragm structure 77 occupied by the rim. In 10 order to achieve a diaphragm width ratio of at least 0.45 to 0.9 with respect to the width of the diaphragm 79 to the width of the structure 77 and therefore to obtain the largest diaphragm possible in the diaphragm structure 77, diaphragm 79 is made relatively large compared to rim 86. 15 With current manufacturing technology, it has been found feasible to have a width of rim 86 of 40 microns, which provides for a diaphragm 79 of 170 microns in a 250 micron-wide diaphragm structure 77 to provide a diaphragm width ratio of 0.68. In a larger diaphragm structure such 20 as 350 microns wide, the pressure sensor assembly 76 can be made stronger by increasing the rim width to 90 microns. Alternatively, it can be made more sensitive by increasing the diaphragm width up to 270 microns. This results in a diaphragm width ratio for a 350 micron-wide 25 device of between 0.49 and 0.77, depending on what combination of sensitivity and strength is desired.

Prior to or after the formation of the rectangular diaphragm 79, a plurality of V-shaped recesses or grooves 91 are formed in the diaphragm structure 77 on the end 30 opposite the end at which the diaphragm 79 is located and on the side opposite the side in which the well 84 is formed. These V-shaped recesses 91 also can be formed in a conventional manner by the use of a conventional etch. It should be appreciated that if desired, the etching can 35 be stopped so that the recesses formed are short of a complete V. By way of example, if the etching for the V-shaped recess was stopped at a depth of 12 microns, the

-10-

bottom of the substantially V-shaped recess or trench 91 would be approximately 8 microns wide.

After the V-shaped or substantially V-shaped recesses have been formed, a P+ diffusion utilizing a suitable material such as boron can be carried out to create a V-shaped region 92 (in the structure 77) which underlies the V-shaped recess 91. Utilizing suitable masking a common layer 93 of a suitable material such as chromium is sputtered into the V-shaped recess 91 to a suitable thickness as for example, 300 Angstroms followed by a layer 94 of a suitable material such as gold of a suitable thickness as for example 3000 Angstroms. The layers 93 and 94 overlie the bottom surface 81 to form pads 96 thereon. In depositing the gold in the V-shaped recess 91 it is desirable to terminate the gold just short of the leftmost extremity of the V-shaped recess as viewed in Figure 8 in order to minimize the likelihood of lead to lead shorting during the dicing operation when a wafer is sawed up into individual sensor chips.

By way of example, the spacing between V-grooves 91 from center to center can be 75 microns with the V-groove having a width of 25 microns and having a typical depth of 18 microns. The metal pads 96 formed by the chromium and gold layers 93 and 94 can have a suitable width as for example, 50 microns with the overlap on each side being approximately 12.5 microns to provide a spacing of approximately 25 microns between adjacent V-shaped pads 96. The bottom of the V-shaped groove can have a total length of approximately 250 microns.

The regions 92 formed from the P+ diffusion have patterns that extend to the right from the three V-shaped recesses 91 as viewed in Figure 8 for a distance so that they underly the approximate midpoint of the diaphragm 81 on opposite sides to provide generally U-shaped portions or resistors 92a which are located on the diaphragm in areas of a maximum stress to provide maximum sensitivity to pressure changes. The resistors 92a are provided with

-11-

opposite ends, one end being connected to one each of the V-grooves and the other end being connected to the center or common V-groove. Contact is made to these P+ diffused regions by the chromium and gold layers 93 and 94
5 hereinbefore described.

The base plate 78 can be formed of a suitable material such as Pyrex supplied by Corning Glassworks and can have the same width as the diaphragm structure 77 but has a length which is less than the length of the
10 diaphragm structure 77 so that the V-shaped grooves 91 are exposed on the underside of the diaphragm structure 77 as shown in Figure 6. It also can have a suitable length such as 850 microns. It is provided with a rectangular recess or cavity 101 having substantially the same size as
15 the diaphragm 79. It can be etched into the Pyrex by suitable means such as a conventional etching process utilizing hydrochloric acid. After the etching has been completed to form the rectangular recess 101 it is bonded to the lower surface of the diaphragm structure 77 to form
20 a hermetic seal with respect to the same so that the cavity 101 underlies the diaphragm 79 and is exposed to the bottom surface 81 of the diaphragm 79. The cavity 101 below the diaphragm 79 serves as a reference pressure chamber and can be filled with a suitable fluid. For
25 example, it can be filled with air to half an atmosphere to provide a partial vacuum. Alternatively, the cavity 101 can be filled to one atmosphere or it can be completely evacuated.

A trifilar lead structure 106 is connected to the
30 rectangular diaphragm structure 77. It has insulated copper leads 107 of a suitable diameter as for example 48AWG soldered into place to the V-shaped recesses 91 so that the leads 107 extend outwardly therefrom and lie in a plane parallel to the plane of the diaphragm structure
35 77. The trifilar lead construction 106 provides insulation around each lead and in addition there is provided additional insulation which surrounds the leads

-12-

and which interconnects the leads into a single unit which can be readily extended through the hypotube forming the flexible elongate member 41.

The pressure sensor assembly 76 is mounted within a 5 cutout 111 provided in the transition housing 51 and secured therein by suitable means such as an epoxy 112 so that the outer surface of the pressure sensor assembly 76 is generally flush with the outer surface of the transition housing 51 (see Figure 3) and so that the 10 diaphragm 79 is exposed to ambient and the leads 106 extend through the flexible elongate member 41 to the proximal extremity 42 of the same where they are connected to the sleeves (not shown) carried by the proximal extremity 42 disposed within the housing 68. Also, the 15 conductors 61 and 62 of the velocity sensing transducer 58 are connected to two of such sleeves (not shown) provided on the proximal extremity 42.

A schematic of the wiring for the pressure sensor assembly 76 is shown in Figure 12. The two generally 20 U-shaped portions 92a on opposite sides of the diaphragm 79 are represented as resistors and are connected to the three leads 107 in the manner shown. One of the first of the outside leads 107 is "SIGNAL OUT" (+) and the second or other outside lead is "SIGNAL OUT" (-) and the third or 25 middle lead is a common lead as shown. This pattern makes it possible to not cross leads and has the third lead going up the middle or center of the die or the diaphragm structure 77. It can be seen that the two resistors 92a connected as shown form a half bridge one of the resistors 30 responds positively to pressure change and the other resistor responds negatively to a pressure change. Thus, as a pressure is supplied to the diaphragm 79, one resistor increases in value and the other resistor decreases in value to provide a voltage change. By 35 applying the same current to both resistors at the same time, temperature effects can be measured because temperature change will affect both of the resistors in

-13-

the same way so that the pressure measurements can be compensated for any changes in temperature which are sensed by the resistors 92a. The changes in resistivity caused by the temperature changes in the resistors will 5 cancel each other out because of the half bridge configuration used. In connection with Figure 12 it can be seen that with the use of three leads it is possible to obtain temperature compensation by utilizing a half-bridge configuration for the pressure sensor. Alternatively, a 10 more precise temperature compensation can be provided by directly measuring the two resistances, and then solving the mathematical equations which relate temperature and pressure to the two sensor resistances.

Operation and use of the guidewire 21 in performing 15 a catheterization procedure such as angioplasty may now be briefly described as follows: Let it be assumed that a guiding catheter (not shown) has been introduced into the femoral artery of the patient 22 shown in Figure 1 with the distal extremity near the desired location in the heart in which it is desired to perform an angioplasty. The guidewire 21 of the present invention is inserted into 20 the guiding catheter. At the time that its distal extremity is in close proximity to the distal extremity of the guiding catheter, the pressure output signal from the guidewire is compared with that of the guiding catheter 25 assuming that the guidewire is provided with pressure sensing capabilities. If there is a difference between the two pressure measurements, the pressure measurement from the guidewire 21 is equalized with that from the guiding catheter at the control console 29. The distal extremity of the guidewire 21 is then advanced so that it 30 is proximal of the stenosis to be treated at which time a pressure measurement is made. After this pressure measurement has been recorded, the distal extremity of the 35 guidewire is then advanced through the stenosis and another pressure measurement made to determine whether the stenosis is severe enough to require treatment by

-14-

angioplasty. Alternatively, the distal extremity of guidewire 21 can be immediately advanced to the distal side of the stenosis rather than making a pressure measurement proximal of the stenosis and thereafter 5 comparing the pressure measurement on the distal extremity being measured by the guidewire 21 with the pressure measurement being provided proximal of the stenosis by the guiding catheter. If it is determined that the stenosis causes a partial occlusion which is severe enough to 10 warrant use of an angioplasty procedure, an angioplasty catheter having a balloon thereon (not shown) can be advanced over the guidewire 21 and advanced into the stenosis to dilate the stenosis. After dilation has occurred, the angioplasty balloon can be withdrawn from 15 the stenosis and pressure measurements can be made proximal and distal of the stenosis to ascertain the effect of the angioplastic treatment. If the pressure measurements indicate that the original dilation by the angioplasty balloon has been inadequate, another balloon 20 catheter as for example, one having a balloon of a greater diameter can then be positioned over the guidewire 21 by utilizing an exchange wire if appropriate. The larger angioplasty catheter can be advanced through the stenosis and inflated to again dilate the stenosis to a larger size 25 after which it can be withdrawn. Thereafter, pressure measurements proximal and distal of the stenosis can again be made to ascertain whether or not the second dilation which has been performed is adequate. The decisions to be made in connection with such procedures can be readily 30 made by use of the control console 29 by observing the traces 33 and 34 on the video monitor 31.

It also should be appreciated that at the same time Doppler velocity measurements can be made by the transducer 58. That information can be used in connection 35 with the pressure measurements to ascertain the need for performing the angioplasty procedure or for determining the efficacy of the angioplasty procedure performed.

-15-

Because of the very small diameters of the guidewires as for example, .018" or .014", it is possible to utilize the guidewire 21 of the present invention with very small coronary vessels in the heart. In connection with the 5 leads from the Doppler transducer 58 it should be appreciated that if desired some of the conductors provided for the Doppler ultrasound transducer can be shared with the wires or conductors provided for the pressure sensor assembly 76. Thus, two of the wires for 10 the pressure sensor can be utilized for the Doppler transducer because the pressure sensor operates at DC or up to a few hundred Hz or KHz whereas the Doppler sensor operates at 10 MHz and above. These frequency ranges can be readily separated by one skilled in the art by using 15 simple filters and the appropriate circuitry.

In connection with the present invention it should be appreciated that rather than bonding the leads 107 into the V-grooves or V-shaped recesses 91, the Pyrex base plate 78 can be formed so it has the same length as the 20 diaphragm structure 77. V-shaped or U-shaped grooves can be formed in the base plate underlying the V-shaped grooves to in effect form little tunnels which can be utilized for receiving the wires 107 and for them to be soldered therein. Such a construction aids in the 25 placement of wires which are of the very small diameter, as for example, 1 mil.

Another embodiment of a guidewire 121 incorporating the present invention is shown in Figure 13. In the guidewire 121, pressure sensor assembly 76 is mounted in 30 a tip housing 122. The tip housing 122 can be substituted at the end cap 57 and threaded into the distal extremity 56 of the coil 54. The tip housing 122 can be formed of a suitable material such as stainless steel having an outside diameter of .018" and a wall thickness of .001" to 35 .002". The sensor assembly 76 can be of the type hereinbefore described and can be mounted in a cutout 123 provided in the tip housing 122 much in the same manner as

-16-

the sensor assembly 76 was mounted in the cutout 111 in the transition housing 51 such as by use of an epoxy 124. An hemispherical end cap 126 formed of a radiopaque material such as palladium or tungsten platinum alloy can 5 be mounted on the distal extremity of the tip housing 122. Alternatively, the end cap 126 can be formed of a non-radiopaque material such as epoxy or silicone rubber.

Thus it can be seen with the embodiment of the guidewire 121 shown in Figure 13, the guidewire 121 can be 10 utilized in the same manner as the guidewire 21 hereinbefore described with the exception of it cannot be used for making velocity measurements because that capability has been removed from the guidewire 121.

Another guidewire 131 incorporating the present 15 invention is shown in Figure 14 in which two pressure sensors 76 have been provided. The sensors 76 have been spaced apart a suitable distance as for example, 3 centimeters with one of the pressure sensors being mounted in the transition housing 51 and the other pressure sensor 20 being mounted in a tip housing 122 of the type shown in Figure 13. With such an arrangement, it can be seen that the distal extremity of the guidewire 131 can be advanced across a stenosis in a vessel with the pressure sensor 76 mounted in the tip housing being distal of the stenosis to 25 measure distal pressure and the pressure sensor 76 in the transition housing 51 being proximal of the stenosis to measure proximal pressure. Thus, it can be seen that it is possible to measure simultaneously the distal pressure and the proximal pressure with respect to a stenosis in a 30 vessel. This may give more accurate measurements than utilizing the proximal pressure being sensed by the guiding catheter.

When using two pressure sensors 76 in the same 35 guidewire as shown in Figure 14, it is possible to utilize the same common wire for both of the transducers, thus making it necessary to provide only five wires rather than six wires for the two pressure sensors.

-17-

Still another guidewire 141 incorporating the present invention is shown in Figure 15 in which a cover 142 is provided for covering the pressure sensor assembly 76 provided in the transition housing 51. The cover is 5 elongate and extends the length of the cutout 111 and is arcuate in cross-section so that it conforms to the conformation of the transition housing 51. The cover 142 can be secured in place by a suitable means such as an adhesive. The cover 142 overlying the pressure sensor 10 assembly 76 is provided with a pin hole 143 which immediately overlies the diaphragm 79. The pin hole 143 can be of a suitable size as for example 2-5 mils in and preferably 3 mils in diameter. The cover 142 serves to prevent the large opening provided by the cutout 111 from 15 collecting blood which could possibly clot. The cover 142 also serves to protect the sensor 76 from damage. It also prevents the sensor 76 from being broken loose during use of the guidewire 141. It should be appreciated that if desired, the volume beneath the cover 142 can be filled 20 with viscous fluid such as oil which can be utilized for transmitting pressure from the pin hole 143 to the diaphragm 81. With a small size pin hole 143, the viscous fluid provided would not have a tendency to bleed out of the transition housing 51. The viscous fluid would 25 be held in place because of the surface tension of the fluid. Because there is a very short distance between the pin hole 143 and the diaphragm 79, there would be very little tendency for the viscous fluid to damp any pressure signal transmitted from the blood in which the guidewire 30 141 is disposed to the diaphragm.

Another guidewire 151 incorporating the present invention is shown in Figure 16 having a transition housing 152 formed of a suitable material such as stainless steel and having an OD of .018" or less. A 35 pressure sensor assembly 76 of the type hereinbefore described is mounted within the bore 153 of the transition housing 152 and is secured therein by mounting the same in

-18-

an epoxy 154 while leaving the area immediately above the diaphragm 79 exposed to a pin hole 156 provided in the transition housing 152. The space overlying the diaphragm 81 exposed to the pin hole 156 can be filled with a
5 viscous fluid 157 such as oil. The viscous fluid 157 can be retained within the desired location by a barrier 158 formed on the proximal side of the pressure sensor 76 having the trifilar lead structure 106 extending therethrough, in sealing engagement therewith. To seal
10 the other end of the bore 153, an intermediate end cap 161 can be provided which is provided with a barrier 182 extending thereacross to seal the bore 153. The intermediate end cap 161 can be bonded to the transition housing 152 by a suitable means such as an adhesive (not
15 shown). The coil 54 can be threaded onto the intermediate end cap 161 and can be threaded onto a tip housing 166 that carries a rounded hemispherical tip 167. With such a construction it can be seen that the pressure sensor assembly 76 is protected within the transition housing
20 152.

In Figure 16A a guidewire 168 is shown which is very similar to the guidewire 151 with the exception that the housing 152 has been provided on the distal extremity of the coil 46 with the tip 167 directly mounted on the
25 housing 152 for closing the bore 153.

In Figure 17 there is shown another embodiment of a guidewire 171 incorporating the present invention which has an integral balloon carried thereby. A guidewire with an integral balloon is described in U.S. Patent No.
30 5,226,421. The guidewire 171 consists of a flexible elongate tubular member 173 in a manner formed of a suitable material such as plastic which is provided with a distal extremity 174. An inflatable balloon 176 is secured to the distal extremity 174 of the flexible
35 elongate member 173 in a manner well known to those skilled in the art. Such a balloon can be formed integral with the distal extremity and can be formed of the same

-19-

material as the flexible elongate tubular member 173. Alternatively, it can be formed of a different material or the same material and be formed as a separate part and secured to the distal extremity 174 by suitable means such
5 as adhesive.

The balloon 176 is provided with a distal extremity which is closed and which is secured to the proximal extremity of a coil spring 178 formed of a radiopaque material such as a palladium or tungsten platinum alloy
10 threaded onto a tip housing 179. The tip housing 179 can be formed in a manner similar to the tip housing 122 shown in Figure 13 having a pressure sensor 76 mounted therein and carrying an end cap 181. The trifilar leads 106 connected to the sensor 76 extend through the coil 178 and
15 through the balloon 176 and through the flexible elongate tubular member 172 to the proximal extremity thereof. A core wire 186 formed of a suitable material such as stainless steel is provided in the flexible elongate member 173 and can be provided with a diameter such as
20 disclosed in Patent No. 5,226,421. The core wire 186 is provided with a tapered portion 186a extending through the balloon which has a distal extremity secured to the housing 179 by a suitable means such as the epoxy utilized for mounting the sensor 76 within the housing. The
25 flexible elongate tubular member 172 is provided with a balloon inflation lumen 187 which can be used for inflating and deflating the balloon 176.

The guidewire 171 with an integral balloon 171 can be utilized in a manner similar to that hereinbefore
30 described for the other guidewires. Rather than deploying a separate catheter with a balloon thereon over the guidewire, the guidewire 171 itself carries the balloon 176 which can be inflated to dilate the stenosis after the proximal and distal pressure measurements have been made
35 by the tip mounted sensor 76. After the balloon 176 has been deflated, the pressure measurement can be made to ascertain the pressure in the distal extremity after

-20-

dilation has occurred. If necessary, the balloon 176 can be re-inflated to perform another dilation of the stenosis to obtain improved blood flow through the stenosis.

After an appropriate dilation has occurred, the 5 guidewire 171 with integral balloon can be removed in a conventional manner. The angioplasty procedure can then be completed in a conventional manner.

From the foregoing, it can be seen that there has been provided an ultra miniature pressure sensor which can 10 be utilized on guidewires having a diameter of .018" and less which can be utilized for making accurate measurements proximal and distal of a stenosis in the coronary vessel. This is made possible because of the small size of the pressure sensor incorporated into the 15 distal extremity of the guidewire. In addition to sensing pressure, flow velocity can also be obtained by the use of a distally mounted velocity transducer provided on the same guidewire as on which the pressure sensor is mounted. Alternatively, additional first and second pressure 20 sensors can be provided on the distal extremity of a guidewire so that pressure measurements can be made simultaneously, proximally and distally of the stenosis. The pressure sensor is constructed in such a manner so that it can be readily incorporated within the confines of 25 a small guidewire as for example, .018" and less. It can be constructed to avoid a large opening in the distal extremity of the guidewire to inhibit or prevent the formation of clots. The pressure sensor also can be protected so that it cannot be readily damaged or broken 30 loose. In addition, where desired, the guidewire can be provided with an integrally mounted balloon on its distal extremity so that the guidewire can be utilized for performing an angioplasty procedure while at the same time facilitating the making of pressure measurements, proximal 35 and distal of the stenosis being treated.

-21-

WHAT IS CLAIMED IS:

1. A guidewire having pressure sensing capabilities for measuring the pressure of liquid in a vessel comprising a flexible elongate member and having proximal and distal extremities and having an outside diameter of .018" or less, said distal extremity of said flexible elongate member being adapted to be disposed in the liquid in said vessel, a housing carried by the flexible elongate member and having a diameter substantially the same as the diameter of the flexible elongate member, said housing having a space therein, a pressure sensor mounted in the space in the housing, the pressure sensor comprising a crystal of semiconductor material having a well therein and forming a diaphragm having a thickness ranging from 2 to 5 microns, said diaphragm being disposed in the housing in a manner so that it is sensitive to changes of pressure in the liquid in the vessel, said diaphragm being rectangular in shape and being bordered by a rim surrounding the well and formed of the crystal of semiconductor material, a backing plate formed of an insulating material bonded to the crystal and serving to reinforce the rim of the crystal of semiconductor material, said backing plate having a cavity therein underlying the diaphragm and in substantial registration with the diaphragm with said cavity serving to provide a pressure reference, said crystal of semiconductor material having at least one diffused region therein formed of an impurity, said diffused region overlying the portion of the diaphragm where deflection will occur whereby upon the application of a pressure to the diaphragm a change in resistivity will occur in the diffused region, conductive means carried by the crystal of semiconductor material and coupled to said at least one diffused region, a power source connected to the conductor means for supplying electrical energy to said at least one diffused region and means measuring the change in resistivity in said at least

-22-

one diffused region to ascertain the pressure being applied to the diaphragm by the liquid in the vessel.

2. A guidewire as in Claim 1 together with means connected to the leads for compensating for temperature changes of the pressure sensor during the time that pressures are being sensed by the pressure sensors.

3. A guidewire as in Claim 1 wherein said diffused region includes first and second diffused portions, said first and second diffused portions overlying said spaced apart portions of the diaphragm and serving as first and second resistor elements having opposite ends.

4. A guidewire as in Claim 3 wherein said crystal of semiconductor material has first and second sides, wherein said well is formed so it extends through said one side together with troughs formed in the crystal of semiconductor material and opening on the opposite side of the crystal of semiconductor material and wherein said conductor means includes leads secured in said troughs and means in said troughs for establishing electrical connections between the leads in the troughs and the first and second diffused portions.

5. A guidewire as in Claim 4 wherein said leads are first and second and third leads secured in said troughs, said first lead being secured to one end of the first resistor element, the second lead being secured to one end of the second resistor element and the third lead being connected to the other ends of the first and second resistor elements to serve as a common lead.

6. A guidewire as in Claim 3 wherein said resistor elements have nominal resistances ranging from 2.5 to 4.5 kilohms and wherein the first and second diffused regions will provide nominally a 100 millivolt output with a

-23-

1 milliamper drive, and a pressure change of 300 mm of mercury.

7. A guidewire as in Claim 1 together with adhesive means carried by the housing for securing said pressure sensor in said housing.

8. A guidewire as in Claim 1 together with a velocity sensor mounted on the distal extremity of the guidewire so as to make possible simultaneous pressure and velocity measurements.

9. A guidewire as in Claim 1 together with first and second coil springs formed of different materials and having proximal and distal extremities, with the proximal extremity of the first coil being secured to the distal extremity of the flexible elongate member, an intermediate housing having proximal and distal extremities disposed between the first and second coil springs, the proximal extremity of the intermediate housing being secured to the distal extremity of the first coil spring, the distal extremity of the intermediate housing being secured to the proximal extremity of the second coil spring and a tip housing mounted on the distal extremity of the second coil spring.

10. A guidewire as in Claim 9 wherein said first named housing is the intermediate housing and wherein said pressure sensor is mounted in the intermediate housing.

11. A guidewire as in Claim 9 wherein said first named housing is the tip housing and wherein said pressure sensor is mounted in the tip housing.

12. A guidewire as in Claim 9 wherein said vessel is an arterial vessel with a stenosis therein and wherein a pressure sensor is mounted in each of the said

-24-

intermediate and tip housings so as to make possible simultaneous pressure measurements on the proximal and distal extremities of the stenosis in the arterial vessel after the guide wire has been advanced through the stenosis.

13. A guidewire as in Claim 1 together with a balloon mounted on the distal extremity of the guidewire.

14. A guidewire as in Claim 1 together with means enclosing the pressure sensor within the housing and having a pin hole opening therein in communication with the well in the semiconductor crystal overlying the diaphragm.

15. A guidewire as in Claim 14 together with a viscous fluid underlying said covering means and serving to establish communication through the pin hole of the pressure of liquid in the vessel encountered by the distal extremity of the guidewire.

-25-

16. A guidewire having pressure sensing capabilities for measuring the pressure of blood in a vessel having a stenosis therein, a flexible elongate element having proximal and distal extremities, first and second housings mounted on the distal extremity of the flexible elongate member and being spaced apart a distance greater than the length of the stenosis, a pressure sensor mounted in each of the housings to make possible simultaneous pressure measurements proximal and distal of the stenosis when the distal extremity of the guidewire is disposed within the vessel with the pressure sensors being disposed on opposite sides of the stenosis in the vessel.

17. A guidewire as in Claim 16 together with first and second coils with the second coil being formed of a material different from the first coil, said first housing being mounted between the first and second coils and the second housing being mounted distally of the second coil.

18. A guidewire having pressure sensing capabilities for measuring the pressure proximal of and distal of a stenosis in a blood carrying vessel comprising a flexible elongate tubular member having proximal and distal extremities, an inflatable balloon secured to the distal extremity, means carried by the flexible elongate member for inflating and deflating the balloon, the balloon having a distal extremity, a housing, means securing the housing to the distal extremity of the flexible elongate tubular member distal of the balloon, the housing having a space therein, a pressure sensor disposed in the housing and having the leads extending through the balloon to the proximal extremity of a flexible elongate member whereby when the balloon is disposed in the stenosis in the vessel, the pressure of the blood distal of the stenosis can be measured.

-26-

19. Apparatus for measuring the pressure proximally and distally of a stenosis in a blood carrying vessel, a flexible elongate member having a diameter of .018" or less and having a distal extremity, a housing having a space therein secured to the distal extremity of the flexible elongate member, a pressure sensor mounted in the housing and leads connected to the pressure sensor and extending through the flexible elongate member, said pressure sensor including a movable diaphragm that is adapted to be placed in communication with the pressure of the blood in the vessel and deflecting in accordance with the pressure of the blood in the vessel, first and second resistive elements carried by the diaphragm, leads coupled to the resistive elements and extending to the proximal extremity of the flexible elongate member, means for supplying a current to the resistive elements and means for measuring changes in voltage as the diaphragm is deflected to ascertain the pressure being measured by the pressure sensor.

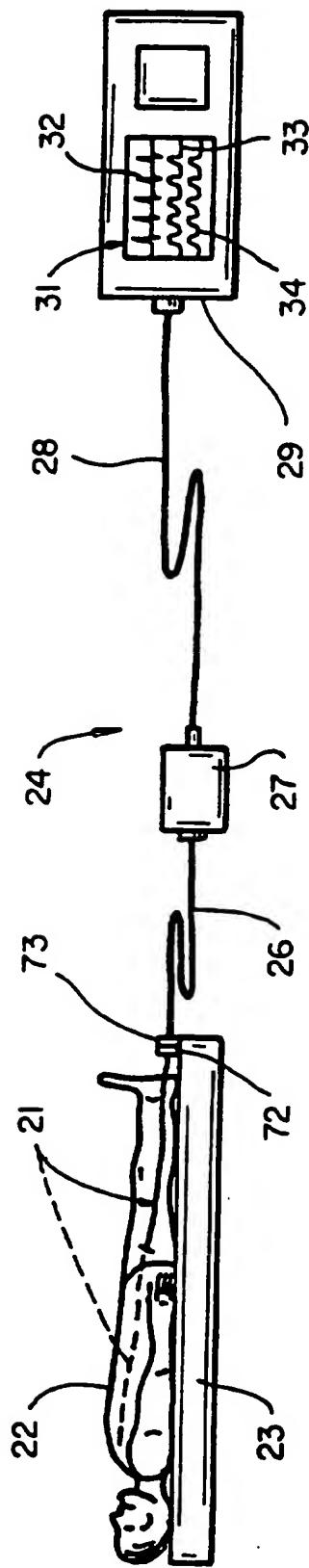
20. A method for making pressure measurements proximal and distal of a stenosis in a vessel carrying blood by the use of a guidewire having a distal extremity and having a diameter of .018" or less and having a pressure sensing capability carried by the distal extremity thereof, advancing the guidewire into the vessel so that its distal extremity is proximal of the stenosis and recording the pressure of the blood in the vessel proximal of the stenosis being measured by the distal extremity of the guidewire, advancing the guidewire through the stenosis, making another pressure measurement of the blood in the vessel distal of the stenosis and making a decision as to whether or not an angioplasty procedure is appropriate for the stenosis.

21. A method as in Claim 20 together with the step of measuring simultaneously the pressure of the blood

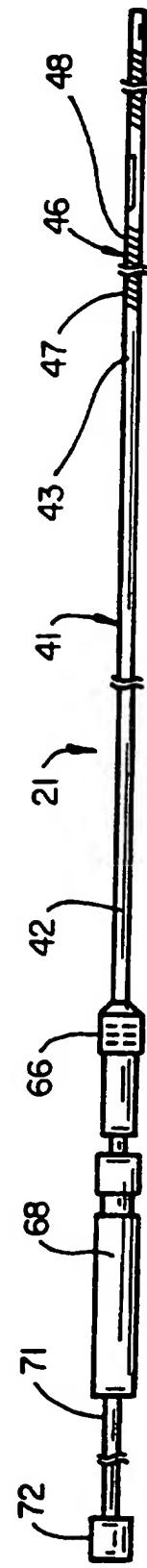
-27-

proximal of the stenosis and the pressure of the blood
distal of the stenosis.

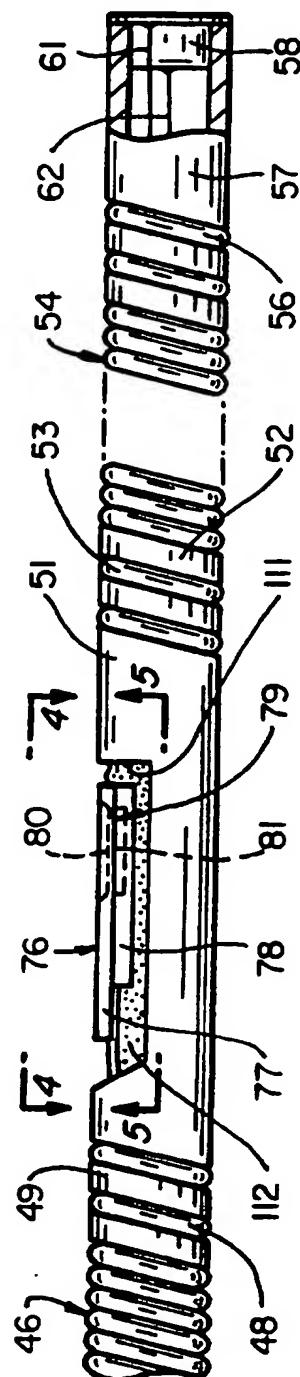
1/6



FIG_1



FIG_2



FIG_3

2/6

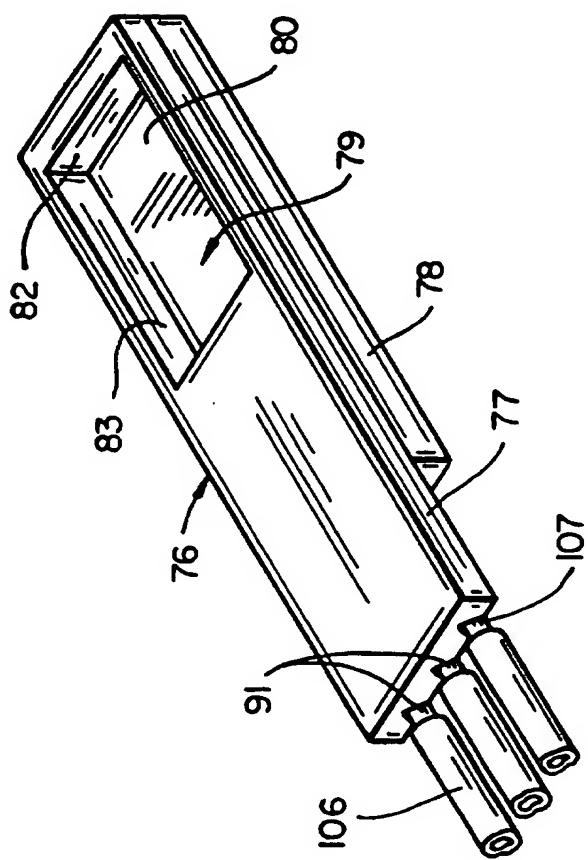


FIG-6

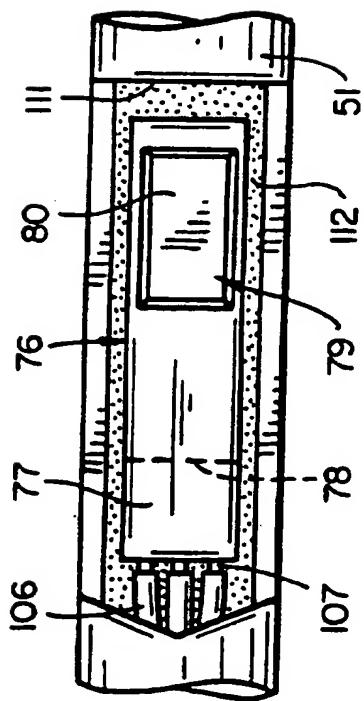


FIG-4

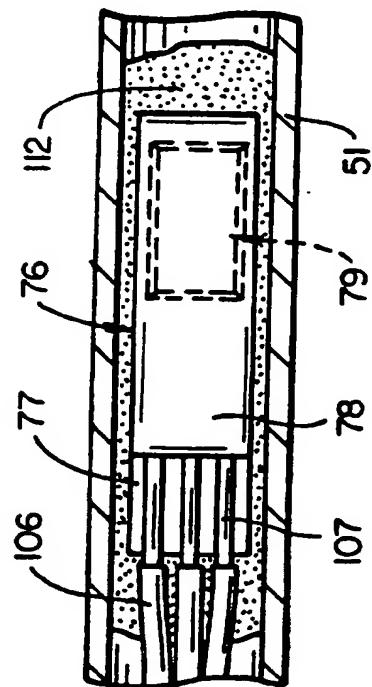
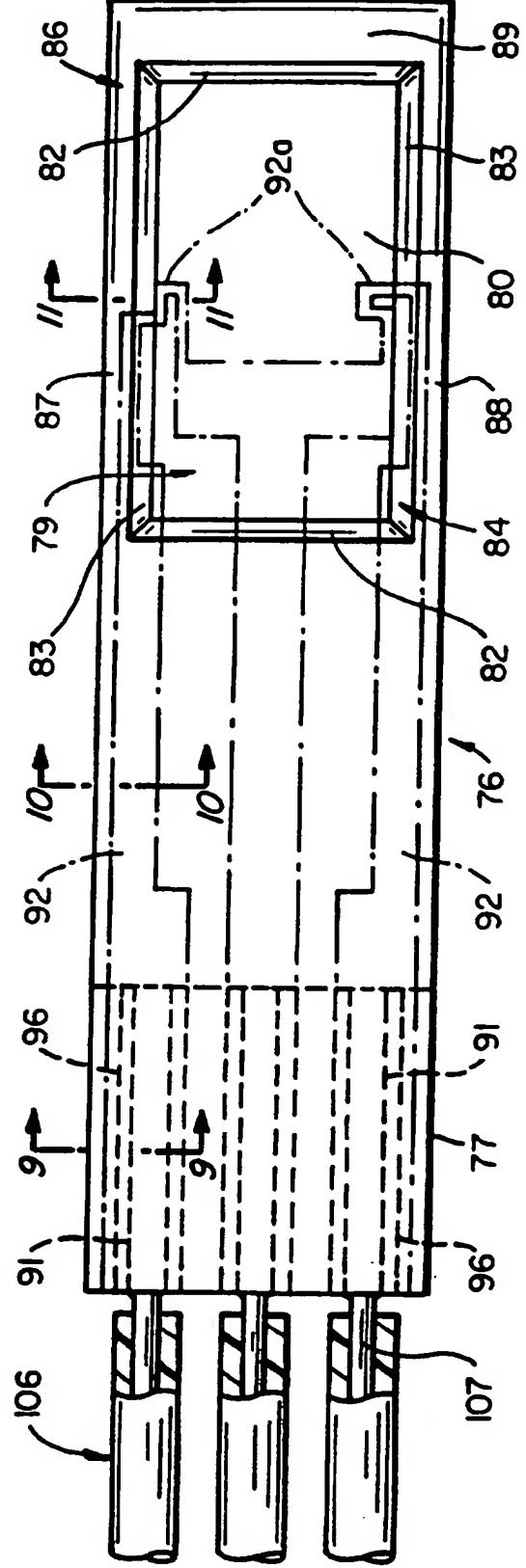
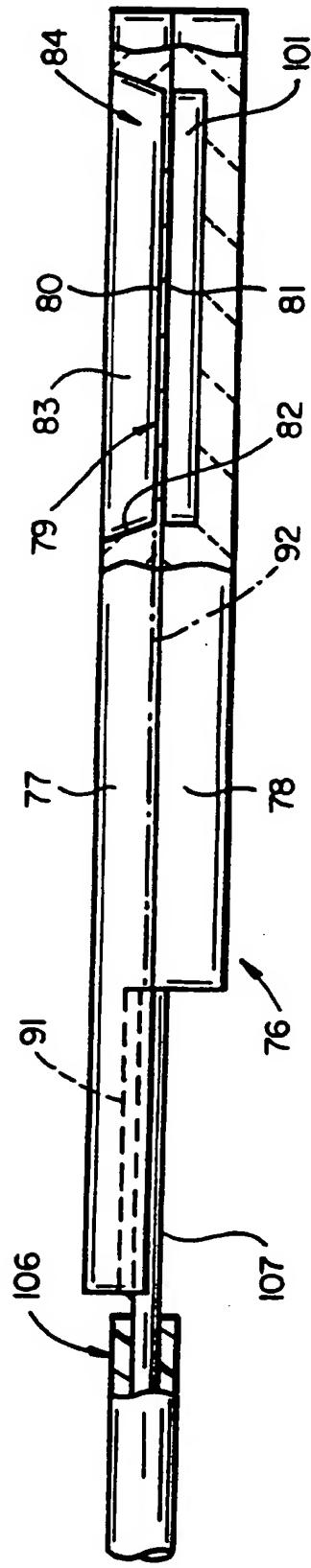
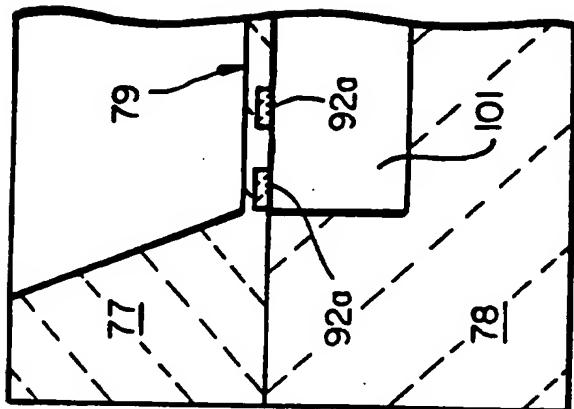


FIG-5

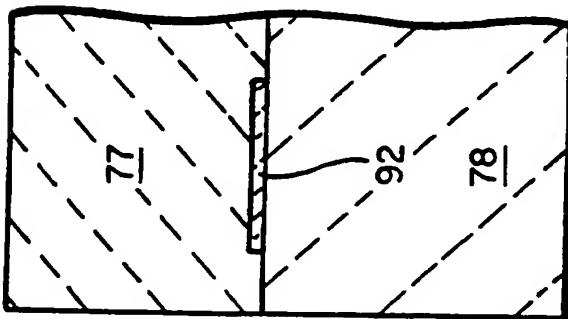
3/6



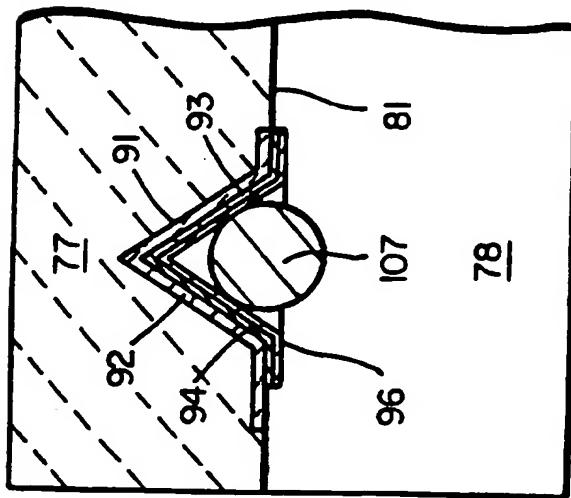
4/6



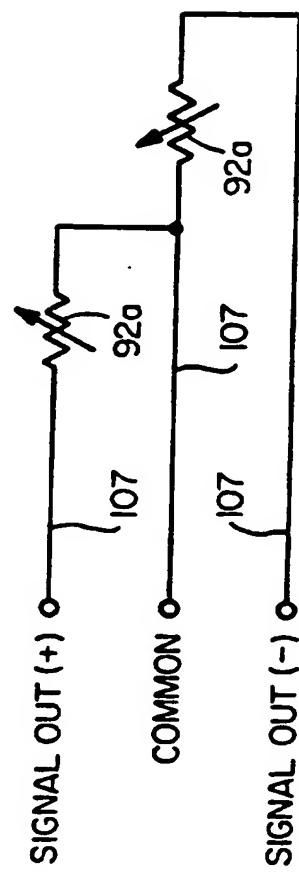
FIG_11



FIG_10

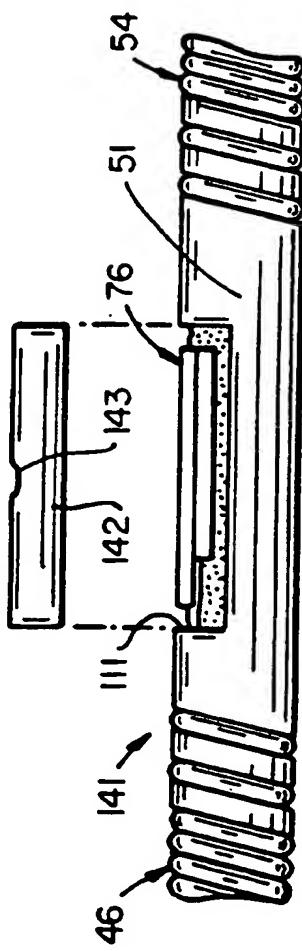
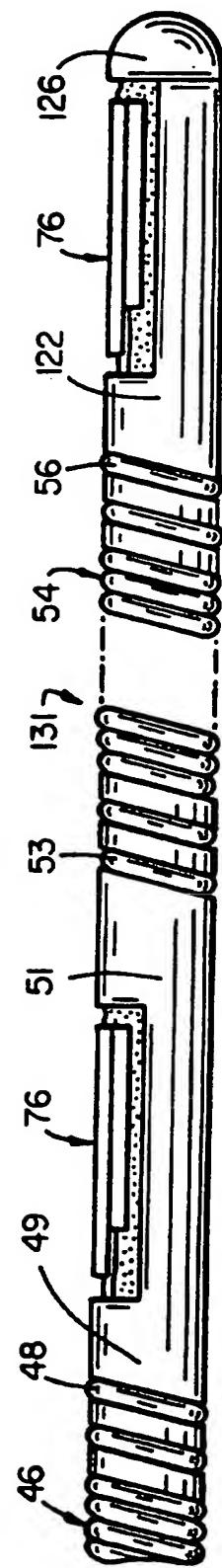
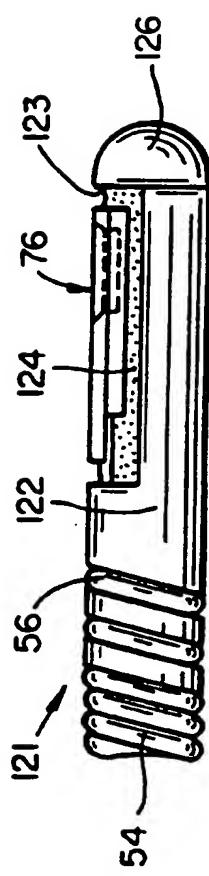


FIG_9

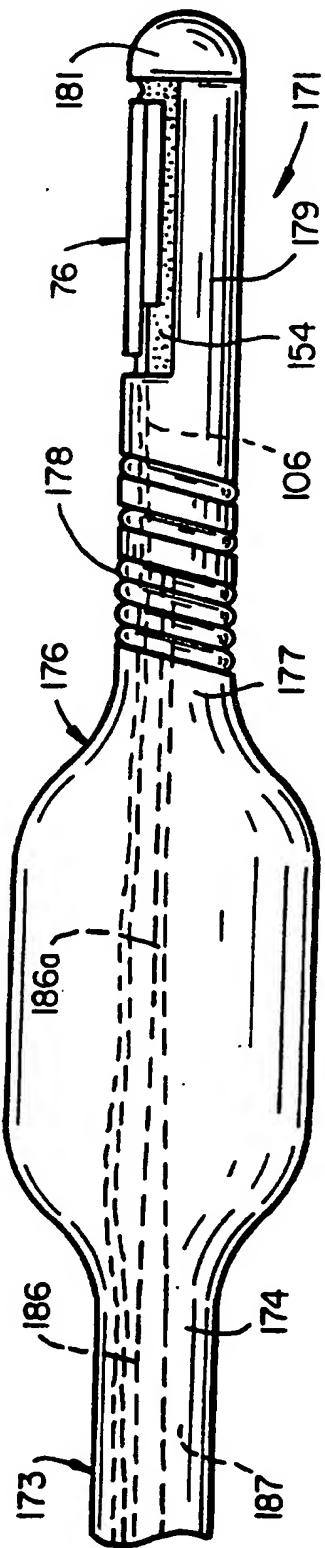
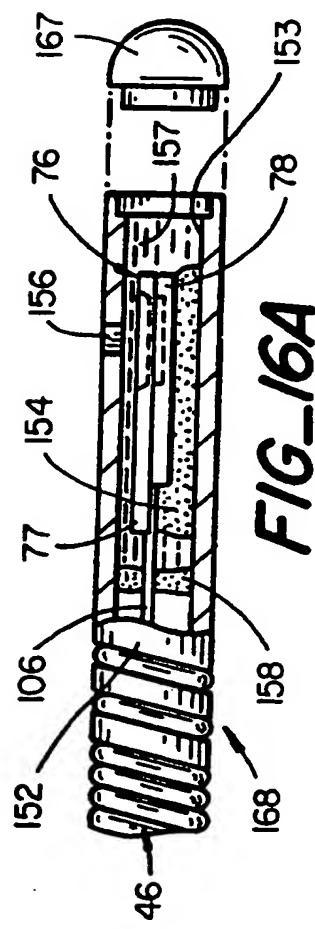
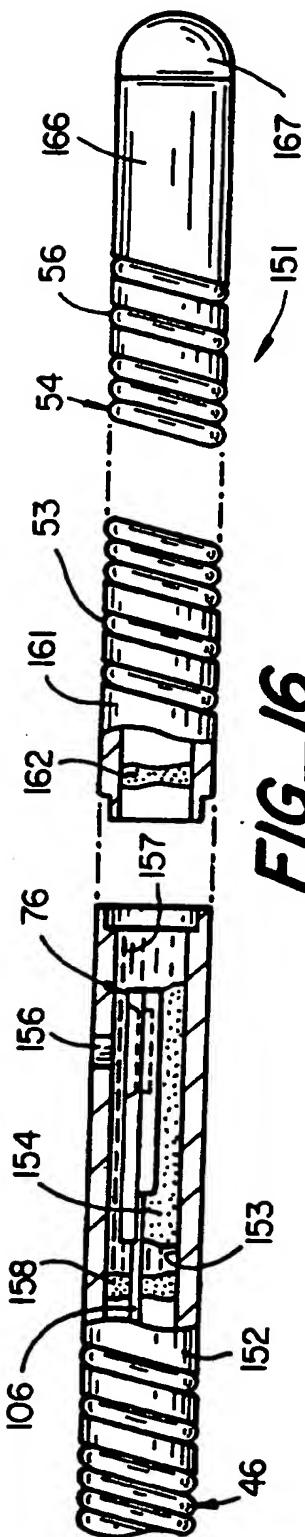


FIG_12

5/6



6/6



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/09898**A. CLASSIFICATION OF SUBJECT MATTER**IPC(6) : A61B 05/00
US CL : 128/673.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 73/720, 721, 726, 727; 128/657, 662.04, 673, 668, 675, 692, 748, 772

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US, A, 5,046,497 (MILLAR) 10 September 1991, see entire document.	19
Y	US, A, 4,733,669 (SEGAL) 29 March 1988, see entire document.	1-10, 20
Y	US, A, 4,274,423 (MIZUNO ET AL.) 23 June 1981, see entire document.	8
Y	US, A, 4,901,731 (MILLAR) 20 February 1990, see column 2, lines 4-16.	1-10, 19, 20
		20

Further documents are listed in the continuation of Box C. See patent family annex.

- * Special categories of cited documents:
 - "A" document defining the general state of the art which is not considered to be part of particular relevance
 - "T" later documents published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
 - "E" earlier document published on or after the international filing date
 - "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reasons (as specified)
 - "N" document referring to an oral disclosure, use, exhibition or other means
 - "P" document published prior to the international filing date but later than the priority date claimed
 - "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
 - "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
 - "Z" document member of the same patent family

Date of the actual completion of the international search

22 SEPTEMBER 1995

Date of mailing of the international search report

01 NOV 1995

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Authorized officer

ROBERT NASSER

Telephone No. (703) 308-3251

Facsimile No. (703) 305-3230

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US95/09898

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Please See Extra Sheet.

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-10, 19-20.

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/09898

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING
This ISA found multiple inventions as follows:

Group I, claims 1-10, 19, and 20.

Group II, claims 1-7, 11, 19, and 20.

Group III, claims 1-7, 9-12, 16, 17 and 19-21

Group IV, claims 1-7, 9, 10, 14, 19, and 20.

Group V, claims 1-7, 9, 10, 14, 15, 19, and 20.

Group VI, claims 1-7, 11, 14, 15 19 and 20.

Group VII, claims 1-7, 11, 13, 18, 19 and 20.

Groups I-VII lack unity with each other in that they are all different species of the same invention.